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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,510	12/05/2003	Kazuhisa Fukushima	032094	7859

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EXAMINER
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GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,510	<b>Applicant(s)</b> FUKUSHIMA ET AL.	
	<b>Examiner</b> Jeanine A. Goldberg	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

1. This action is in response to the papers filed August 18, 2006. Currently, claims 2-5, 7 are pending.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
  - a. The terminal disclaimer filed August 18, 2006 has been reviewed and approved.
3. Any objections and rejections not reiterated below are hereby withdrawn.

***Maintained Rejections***

***Election/Restrictions***

4. Applicant's election without traverse of Group 1, Claims 1-5 in the paper filed January 3, 2006 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

***Priority***

5. This application claims priority to Japanese Appln No. 2002-353559, filed December 5, 2002.

It is noted that a translation of the foreign document has not been received.

***Drawings***

6. The drawings are acceptable.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2, 4-5, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al. (US 6,429,027, August 6, 2002).

Chee teaches composite arrays using microspheres and methods for decoding microsphere array sensors. Chee teaches a method of decoding an array composition comprising providing an array composition and adding a plurality of decoding binding ligands to the composite array composition to identify the location of at least a plurality of the bioactive agents (col. 3-4, lines 65-3). Chee teaches a coding/decoding system is required to identify the bioactive agent at each location in the array (col. 5, lines 30-35).

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The decoding systems makes use of a decoding binding ligand (DBL), generally directly labeled, that binds to either the bioactive agent or to identifier binding ligands (IBLs) attached to the beads and/or positional decoding (col. 5, lines 35-40). Chee teaches the binding should be sufficient to remain bound under the conditions of the decoding step, including wash steps (col. 15, lines 5-10). The DBLs include proteins particularly including antibodies or fragments. Antigen-antibody pairs are useful (col. 15, lines 20-25). Chee teaches using different IBLs to encode each bioactive agent (col. 16, lines 35-40). The identification of the location of the individual beads is done using one or more decoding steps comprising a binding between the labeled DBL and either the IBL or the bioactive agent (col. 19, lines 45-50). Chee teaches a spatial or positional coding system may be used where each subarray is an "area code" that can have the same tags of other subsarrays, that are separated by virtue of the location of the subarray (col. 21, lines 60-65).

Chee teaches that a key components of the invention is the use of a substrate/bead pairing that allows the association or attachment of the beads at discrete sites on the surface of the substrate such that the beads do not move during the course of the assay (col. 9, lines 40-45).

Chee teaches that the beads or microspheres may be plastics, ceramics, glass, polystyrene, methylstyrene, paramagnetic materials, for example (col. 9, lines 24-26)(limitations of Claim 4).

Chee teaches the target sequence may be a portion of a gene, a regulatory sequence, genomic DNA, cDNA, RNA (col. 13, lines 20-30)(limitations of Claim 5).

### **Response to Arguments**

The response traverses the rejection. The response asserts that the IBL/DBL combinations of Chee appear to be utilized for the purpose of binding a microsphere to another bead, called a "decoder bead". This argument has been considered but is not convincing because the IBL/DBL is used for positional decoding on arrays. Chee teaches that the key component of the invention is the use of a substrate/bead pairing that allows the association or attachment of the beads at discrete sites on the surface of the substrate such that the beads do not move during the course of the assay (col. 9, lines 40-45). This IBL/DBL binding is between proteins, or antigen-antibody pairs (col. 15, lines 20-25). Chee teaches that the arrays are made by adding a solution or slurry comprising the beads to a surface containing the sites for attachment of the beads (col. 17, lines 35-40). While Chee teaches that the DBL may be attached to a bead, this is a substrate encompassed within the claims.

Thus for the reasons above and those already of record, the rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. (US 6,429,027, August 6, 2002) in view of Collier et al. (US Pat. 5,985,548, November 1999).

Chee teaches composite arrays using microspheres and methods for decoding microsphere array sensors. Chee teaches a method of decoding an array composition comprising providing an array composition and adding a plurality of decoding binding ligands to the composite array composition to identify the location of at least a plurality of the bioactive agents (col. 3-4, lines 65-3). Chee teaches a coding/decoding system is required to identify the bioactive agent at each location in the array (col. 5, lines 30-35). The decoding systems makes use of a decoding binding ligand (DBL), generally directly labeled, that binds to either the bioactive agent or to identifier binding ligands (IBLs) attached to the beads and/or positional decoding (col. 5, lines 35-40). Chee teaches the binding should be sufficient to remain bound under the conditions of the decoding step, including wash steps (col. 15, lines 5-10). The DBLs include proteins particularly

including antibodies or fragments. Antigen-antibody pairs are useful (col. 15, lines 20-25). Chee teaches using different IBLs to encode each bioactive agent (col. 16, lines 35-40). The identification of the location of the individual beads is done using one or more decoding steps comprising a binding between the labeled DBL and either the IBL or the bioactive agent (col. 19, lines 45-50). Chee teaches a spatial or positional coding system may be used where each subarray is an "area code" that can have the same tags of other subarrays, that are separated by virtue of the location of the subarray (col. 21, lines 60-65). Chee teaches that a key components of the invention is the use of a substrate/bead pairing that allows the association or attachment of the beads at discrete sites on the surface of the substrate such that the beads do not move during the course of the assay (col. 9, lines 40-45). Chee teaches that the beads or microspheres may be plastics, ceramics, glass, polystyrene, methylstyrene, paramagnetic materials, for example (col. 9, lines 24-26)(limitations of Claim 4). Chee teaches the target sequence may be a portion of a gene, a regulatory sequence, genomic DNA, cDNA, RNA (col. 13, lines 20-30)(limitations of Claim 5).

Chee does not specifically teach a method of stirring beads.

However, Collier teaches beads and test mixtures are agitated to assure contact with the bead supports (see Example 2).

Therefore, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to have added an agitation or stirring step to the bead method of Chee for the expected benefits taught by Collier. Collier specifically teaches the ordinary artisan would be motivated to agitate bead and test mixtures to assure



contact with the bead supports. Thus, in order to ensure contact of the beads and mixtures, the ordinary artisan would have included an agitation step.

### **Response to Arguments**

The response traverses the rejection. The response asserts Collier does not disclose or suggest that target biopolymers and beads are put in a reservoir together with a buffer solution and are stirred using a physical, electrical or chemical means. This argument has been considered but is not convincing because Collier specifically teaches stirring steps to ensure contact of beads and the nucleic acids.

The response further asserts that even if Collier teaches a stirring step, there is no motivation to combine Chee and Collier. This argument has been reviewed but is not convincing because Collier specifically teaches the benefits for an agitation or stirring step as ensuring mixtures contact the beads to allow binding.

Thus for the reasons above and those already of record, the rejection is maintained.

### ***Conclusion***

**10. No claims allowable over the art.**

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.



**Jeanine Goldberg**  
**Primary Examiner**  
October 30, 2006